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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,082	06/06/2001	Daniel J. Capon	50130-G	9120

7590 12/16/2002
John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER

KETTER, JAMES S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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6

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Commissioner of Patents and Trademarks

--See attached--

Office Action Summary

Application No.

09/875,082

Applicant(s)

CAPON ET AL.

Examiner

James S. Ketter

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,10,13-17,28,31,34,35,37,72,74,76,83 and 84 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4,10,13-17,28,31,34,35,37,72,74,76,83 and 84 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

Art Unit: 1636

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74 and 83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 13-17, 30, 37, 38, 40, 45, 70 and 71 of U.S. Patent No. 5,837,464, matched up as: instant claims 1, 4 and 10 over patented claim 1; instant claims 2, 3 and 13-17 over patented claims 2, 3 and 13-17, respectively; instant claims 28 and 31 over 30; and instant claims 34, 35, 37, 72, 74 and 83 over patented claims 37, 38, 40, 70, 71 and 45, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the instant claims encompasses the respective patented claim.

Claims 1, 14, 28, 34, 35, 37, 72, 74, 83 and 84 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 7, 8, 10, 24, 26, 6 and 6, respectively, of U.S. Patent No. 5,837,464. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the instant claims encompasses the respective patented claim.

Art Unit: 1636

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74, 76, 83 and 84 are rejected under 35

U.S.C. 112, first paragraph, because the specification, while being enabling for vectors wherein the expression of the indicator gene is dependent upon the patient-derived segment, does not reasonably provide enablement for vectors wherein the expression of the indicator gene does not depend upon the patient-derived segment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

It is apparent that, for function of the claimed invention as disclosed, and therefore for use of the claimed invention as disclosed, there must be a functional connection between the patient-derived segment and the indicator gene. No guidance is offered by the specification toward rendering functional a vector not possessing such a functional connection, nor does the art offer any such guidance. It is difficult to imagine how empirical experimentation would overcome a functional disconnection between these elements. As such, this experimentation would be undue experimentation.

Art Unit: 1636

Claims 1-4, 10, 13-17, 28, 31, 34, 35, 37, 72, 74, 76, 83 and 84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The genus of viruses encompassed by the instant claims is vast, including at least all pathogenic viruses. Clearly, viruses have a great variety of different modes of replication, genomic organization, types of genes actually present or absent in the viral genome, protein capsid components, and so forth. No clear similarities exist in these respects that would be representative of all viruses. Thus, both the structures and the functions of viral genes are variable and non-conformant to an overall scheme or pattern. Furthermore, there does not appear to have been a complete characterization of all pathogenic viruses in existence. In view of these factors, it would not have been apparent to one of skill in the art at the time of filing that a structure-function relationship would have been known for all viruses. As such, one of skill would not have recognized that Applicants were in possession of the full scope of the claimed invention at the time of filing.

Certain papers related to this application may be submitted to the directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to

Art Unit: 1636

this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.


Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

Questions regarding formalities and processing of the case should be directed to Zeta Adams, whose telephone number is (703) 305-3291.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
December 9, 2002



**JAMES KETTER
PRIMARY EXAMINER**